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(54) **PROCESS FOR PREPARATION OF ISOSULFAN BLUE**

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(58) **Field of Classification Search**
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(57) **ABSTRACT**

A process for the preparation of isosulfan blue (Active Pharmaceutical Ingredient) is provided. A process is also provided for preparation of the intermediate, 2-chlorobenzaldehyde-5-sulfonic acid, sodium salt of formula (2), used in the preparation thereof and a procedure for the isolation of benzaldehyde-2,5-disulfonic acid, di-sodium salt of the formula (3). Also provided is a process for the preparation of an isoleuco acid of formula (4), which upon mild oxidation gives rise to isosulfan blue of pharmaceutical grade which can be used for preparation of pharmaceutical formulations. The isolation and purification procedures provided in the process provide substantially pure isosulfan blue with HPLC purity 99.5% or greater.

18 Claims, No Drawings